**NOT FOR PUBLICATION**

**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**

| | | |
|---|---|---|
| IN RE SCHERING-PLOUGH CORP. | : | |
| INTRON/TEMODAR CONSUMER | : | Master File No. |
| CLASS ACTION, | : | 2:06-cv-5774 (SRC) |

**OPINION**

**CHESLER, U.S.D.J.**

This matter comes before the Court on the motion to dismiss the Amended Consolidated Class Action Complaint ("Amended Complaint") filed by various third-party payor ("TPP") Plaintiffs[1] on September 9, 2009. The moving Defendants are Schering-Plough Corporation, Schering Sales Corporation, Schering Corporation and Integrated Therapeutics Group, Inc.

[1] The Plaintiffs are International Brotherhood of Teamsters Local No. 331 Health & Welfare Trust Fund ("Local 331"), Heavy and General Laborers' Local Union 472/172 Welfare Fund ("Local 472"), United American Insurance Company ("UAI") and Blue Cross Blue Shield of Alabama ("BCBSAL"). As these four parties are the plaintiffs named in this putative class action, the Court will refer to them collectively as "Named Plaintiffs" in this Opinion.

The Amended Complaint before the Court does not name as plaintiffs various consumers who had appeared on the caption of the original Consolidated Class Action Complaint (the "Complaint"). A separate Amended Consolidated Class Action Complaint has been filed by one of those consumer plaintiffs, Angela F. Montgomery, on behalf of a proposed class of consumers. The Court addresses the sufficiency of the "Montgomery Amended Complaint" in an accompanying Opinion adjudicating the separately-filed motion to dismiss that pleading.

(collectively "Schering") [docket entry no. 218] and Individual Defendants Richard J. Kogan, William K. Heiden and Mary Naughton [Docket Entry No. 220]. Named Plaintiffs have opposed the motion. For the reasons expressed below, the Court will grant the motion and dismiss the Amended Complaint in its entirety.

## I. BACKGROUND

As the parties are well-aware, this putative class action concerns an allegedly improper marketing scheme by Schering relating to the promotion and sale of various drugs for off-label use. The drugs at issue are Intron-A, PEG-Intron, Rebetol (the "Intron Franchise Drugs") and Temodar. (When appropriate, the Court will refer to the drugs collectively as the "Subject Drugs.") The four Named Plaintiffs bring the action on behalf of a proposed class of health and welfare funds and other TPPs. The facts giving rise to this action are set forth extensively in the Court's July 10, 2009 Opinion, issued in connection with the dismissal of the original Complaint, and the Court refers the reader to the Factual Background section of that Opinion for reference. See In re Schering-Plough Corp. Intron/Temodar Consumer Class Action ("Schering I"), No. 06-5774, 2009 WL 2043604, at *1-5 (D.N.J. July 10, 2009).

More pertinent to an understanding of the instant evaluation of the claims as pled in the Amended Complaint is a summary of the procedural background and the Court's disposition of the motion to dismiss the Complaint. The Court granted Defendants' motion to dismiss all nine claims asserted in the Complaint, which included federal and state RICO claims, a claim under the New Jersey Consumer Fraud Act and various common law causes of action. The crux of the Court's analysis was that the Complaint failed to allege facts that would plausibly support

Plaintiffs' assertions that (1) they had been injured in a way capable of remedy under the causes of action they sought to prosecute and (2) their loss was causally connected to Defendants' alleged misconduct. The Court, however, did provide Named Plaintiffs leave to file an amended pleading. Pursuant to Federal Rule of Civil Procedure 15, Named Plaintiffs filed their Amended Complaint on September 9, 2009. The Amended Complaint, though expanding on the factual allegations, substantially pares down the legal theories of recovery Named Plaintiffs wish to pursue. It asserts four causes of action: (1) a claim under the federal Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961, et seq. (Count I); (2) a claim under New Jersey RICO, N.J.S.A. § 2C:41-1, et seq. (Count II); (3) a common law claim for tortious interference with contractual relations (Count III); and (4) unjust enrichment (Count IV).

On the instant motion to dismiss, the Court must evaluate whether Plaintiffs have now come forward with factual allegations that cure the deficiencies identified in the July 10, 2009 Opinion as to the claims in Counts I, II and IV of the Amended Complaint, which re-plead claims asserted in the earlier pleading, and that sustain Named Plaintiffs' newly introduced tort claim in Count III.

## II. DISCUSSION

Defendants move for the dismissal of the entire Amended Complaint on three grounds: (1) it fails to allege that any of the Named Plaintiffs sustained an injury-in-fact; (2) it fails to allege proximate causation; and (3) it fails to allege that Defendants engaged in conduct actionable under any of the substantive causes of action.

As it did on review of the Complaint, the Court must of course commence its analysis with the issue of injury-in-fact, because injury-in-fact is essential to a party's standing under Article III of the Constitution to bring a particular claim for relief. Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 96-97 (1998); United Food and Commercial Workers Union Local 751 v. Brown Group, Inc., 517 U.S. 544, 551 (1996); Interfaith Cmty. Org. v. Honeywell Int'l, 399 F.3d 248, 254 (3d Cir. 2005). Article III standing is jurisdictional. Ballentine v. United States, 486 F.3d 806, 810 (3d Cir. 2007). Before reaching the question of whether the Named Plaintiffs have stated prima facie claims, the Court must satisfy itself that each one has demonstrated that it meets the fundamental jurisdictional requirement that it has standing to sue. Id. (citing Raines v. Byrd, 521 U.S. 811, 818 (1997)); see also Joint Stock Soc'y v. UDV N. Am., Inc., 266 F.3d 164, 175 (3d Cir.2001) ("Constitutional standing is a threshold issue that we should address before examining issues of prudential standing and statutory interpretation.").

**A. Standing**

Insofar as Defendants' motion to dismiss challenges Named Plaintiffs' standing to bring their two RICO and two common law claims, it implicates Federal Rule of Civil Procedure 12(b)(1). Ballentine, 486 F.3d at 810. Thus, the standard of review applicable to Rule 12(b)(1) motions, as set forth in the July 10, 2009 Opinion, will govern here. See Schering I, 2009 WL 2043604, at *6.

Defendants argue that although the Amended Complaint expands on factual allegations relating to Schering's marketing of the Subject Drugs, it fails to contain any facts demonstrating that Named Plaintiffs were somehow injured by these allegedly improper marketing practices. They contend that Named Plaintiffs' claim of injury is too speculative to invoke the jurisdiction

of this Court under Article III. In other words, they challenge Named Plaintiffs' constitutional standing.

Article III of the Constitution limits the power of federal courts to "Cases" or "Controversies." Lujan v. Defenders of Wildlife, 504 U.S. 555, 559-60 (1992). The Supreme Court has articulated what Article III standing entails:

> Over the years, our cases have established that the irreducible constitutional minimum of standing contains three elements. First, the plaintiff must have suffered an "injury in fact"-an invasion of a legally protected interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical. Second, there must be a causal connection between the injury and the conduct complained of - the injury has to be fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court. Third, it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.

Id. at 560 (internal quotations, alterations and citations omitted). In Lujan, the Supreme Court stressed the injury-in-fact requirement that the harm claimed be "particularized," or as it explained, that it affect the plaintiff personally. Id. at 561 n.1. "[T]he 'injury in fact' test requires more than an injury to a cognizable interest. It requires that the party seeking review be himself among the injured." Id. at 563 (quoting Sierra Club v. Morton, 405 U.S. 727, 734-35 (1972)).

A plaintiff seeking redress in federal court bears the burden of establishing it has standing to sue. Id. at 561; Warth v. Seldin, 422 U.S. 490, 508 (1975). To do this, it must support each of the three elements enumerated above in the same manner required to sustain any other burden at the particular stage of litigation in which standing is challenged. Lujan, 504 U.S. at 561. Relevant to the instant motion, standing may be demonstrated at the pleading stage based upon

the complaint's factual allegations of injury resulting from defendant's conduct. Id. In assessing whether Named Plaintiffs have, by the allegations of the Amended Complaint, established standing to sue, the Court will accordingly apply the standard of reviewing a complaint's sufficiency under Rule 8(a), as enunciated by the Supreme Court in Bell Atlantic Corp. v. Twombly, 550 U.S. 544 (2007) and Ashcroft v. Iqbal, 129 S.Ct. 1937 (2009). These cases held that viable complaints must be held to a plausibility standard. Iqbal, 129 S.Ct. at 1949; Twombly, 550 U.S. at 570. Under this standard, a complaint must contain sufficient factual allegations, which taken as true, raise a right to relief above the speculative level. Iqbal, 129 S.Ct. at 1949; Twombly, 550 U.S. at 589. While the complaint need not demonstrate that a defendant is *probably* liable for the wrongdoing, allegations that give rise to the mere *possibility* of unlawful conduct will not do. Iqbal, 129 S.Ct. at 1949; Twombly, 550 U.S. at 557.

To determine whether concrete and particularized injury-in-fact is supported by the factual allegations of the Amended Complaint, the Court must evaluate the injury claimed vis-a-vis each legal source of relief asserted. Lujan, 504 U.S. at 560. The injury must be an invasion of a legally protected interest. Id.; see also Warth, 422 U.S. at 500 (holding that standing . . . often turns on the nature and source of the claim asserted."); see also Bennett v. Spear, 520 U.S. 154, 162 (1997) ("a plaintiff's grievance must arguably fall within the zone of interests protected or regulated by the statutory provision or constitutional guarantee invoked in the suit.").

**B. RICO Claims**

The causes of action asserted by Plaintiffs in Counts I and II of the Amended Complaint arise under the federal RICO statute and the New Jersey RICO statute, respectively. While RICO imposes additional standing requirements, limiting the availability of redress under the statute to persons who have suffered an injury to business or property as result of racketeering activity, 18 U.S.C. § 1964(c), it does not, and indeed cannot, dispense with the threshold Article III requirements. Linda R.S. v. Richard D., 410 U.S. 614, 616-17 (1973) (holding that while Congress may expand the types of "personal stakes" which are capable conferring standing, the plaintiff in question must nevertheless demonstrate such a personal stake); see also Maio v. Aetna, Inc., 221 F.3d 472, 482 n.7 (3d Cir. 2000) (holding that statutory standing under RICO must be satisfied in addition to Article III requirements). Indeed, "broadening the categories of injury that may be alleged in support of standing is a different matter from abandoning the requirement that the party seeking review must himself have suffered an injury." Sierra Club, 405 U.S. at 738. Given RICO's specific definition of what constitutes a legally protectible interest under the statute, the Article III question of whether Named Plaintiffs have pled concrete and particularized injury sufficient to establish standing under RICO cannot be addressed without also considering the kind of injury which is legally cognizable by virtue of the statute. See

Warth, 422 U.S. at 500 ("The actual or threatened injury required by Art. III may exist solely by virtue of 'statutes creating legal rights, the invasion of which creates standing . . . .'") (quoting Linda R.S., 410 U.S. at 617 n.3)).[2]

In its July 10, 2009 Opinion, the Court provided a lengthy analysis of the legal interests that RICO was designed to protect.[3] That analysis delineated the contours of cognizable RICO injury to business or property as applied to this case. See Schering I, 2009 WL 2043604, at *8-22. The Court here summarizes its earlier holdings on this issue as follows:

The Court rejected Named Plaintiffs' theory of injury based on merely paying for a Subject Drug which had been marketed and prescribed for an off-label use. It reasoned that off-label promotion may violate the federal Food, Drug and Cosmetics Act ("FDCA"), but it is not inherently fraudulent and thus not in itself the kind of conduct proscribed by RICO. The Court held that off-label promotion alone, that is, without some further allegation that the promotion

[2] The Third Circuit observed in Maio that matters of RICO statutory standing under 18 U.S.C. § 1964(c) are typically addressed in the context of Rule 12(b)(6), meaning the presence or absence of the statutory preconditions to suit concern whether the plaintiff has stated a claim for relief as opposed to whether the plaintiff had a personal stake in the wrongdoing complained of. Maio, 221 F.3d at 482 n.7. It also observed that where the standing issue concerns the plaintiff's personal stake, or injury-in-fact, then the dismissal of the RICO claim would implicate a court's jurisdiction under Article III, and thus fall within the rubric of Rule 12(b)(1). Id. This Court highlights this distinction because, although the Court must take into account what constitutes injury under RICO, its holding ultimately turns on Named Plaintiffs' ability to demonstrate a personal stake in the marketing scheme they allege violates RICO.

[3] The Court's conclusions regarding what does, and does not constitute an injury capable of redress under RICO injury applies to both the federal and state causes of action for racketeering. As the Court noted in its July 10, 2009 Opinion, it appropriately evaluates the federal RICO and New Jersey RICO claims as contemplating the same type of redressable injury. See Schering I, 2009 WL 2043604, at *7 (citing Cetel v. Kirwan Fin. Group, Inc., 460 F.3d 494, 510 (3d Cir. 2006)).

involved some dishonesty about the drug's qualities or suitability to treat an illness, could not give rise to injury within the meaning of RICO. Informed by the well-established principle that injury under RICO concerns concrete financial loss to a party's business or property, the Court concluded that adequately pleading injury requires allegations that Named Plaintiff TPPs paid for Subject Drugs that were inferior and/or worth less than what Plaintiffs paid. The inferiority of the product could be alleged, for example, by pleading facts asserting that the drug was either ineffective for the indication for which it was prescribed or unsafe. On the matter of effectiveness, the Court cautioned that a lack of data or evidence affirmatively proving that a Subject Drug was effective in treating a condition was not the same as the actual ineffectiveness of the Subject Drug. The former would amount to an alternative way of expressing that the Defendants had violated the FDCA, as the Subject Drugs' effectiveness for a particular use had not been vetted through FDA approval. The same distinction applies to Named Plaintiffs' claims of safety. Moreover, the Court held that the TPPs' asserted "overpayment" for the Subject Drugs based on the existence of cheaper alternative medications or treatments that were available to a beneficiary's prescribing doctor does not make the product received inferior or worth less and therefore does not constitute RICO injury. The Court also rejected Named Plaintiffs' "fraud on the market" theory of economic loss, that is, that Schering's program of off-label promotion drove up the demand for the Subject Drugs and thus inflated the prices which Named Plaintiffs paid.

As noted earlier, constitutional standing also requires that the injury be causally linked to some action or conduct by Defendants, that is be fairly attributable to their alleged wrongdoing. Specific to their RICO claims, the Named Plaintiffs accuse Defendants of having engaged in mail

and wire fraud in the promotion of the Subject Drugs as well as bribery to induce physicians to prescribe the Subject Drugs for off-label uses. The Court again stresses that, even in a suit brought as a putative class action, those who seek to represent the class must themselves meet the essential standing requirement of having personally sustained the injury for which redress is sought. The Named Plaintiffs must allege "that they personally have been injured, not that injury has been suffered by other, unidentified members of the class . . . ." Lewis v. Casey, 518 U.S. 343, 347 (1996).

The Court has summarized its analysis of injury under RICO as applied to this case to be clear about the framework in which it analyzes Named Plaintiffs' standing to invoke the authority of this Court under Article III of the Constitution to resolve their alleged grievance. For the RICO claims to survive, each Named Plaintiff must at a minimum allege that (1) it paid for the Subject Drugs to treat an off-label indication for which the drugs were ineffective and/or unsafe and thus worth less than what was paid and (2) the diminished value of the Subject Drugs was caused by Schering's marketing practices.

Named Plaintiffs argue that the Amended Complaint plausibly states that they made actual purchases of the Subject Drugs for ineffective purposes as a result of prescriptions written by physicians influenced by Schering's misrepresentations about the Subject Drugs and/or by Schering's campaign of illegally inducing physicians to prescribe the Subject Drugs. The Amended Complaint indeed contains detailed allegations about the marketing practices at issue. For example, it avers that:

- Schering represented to doctors that Temodar had the ability to cross the blood-brain barrier, knowing that it did not have evidence to support such a claim. (Am. Compl., ¶¶ 5, 192-197.)

- Schering's own Senior Project Manager for Temodar, Jorge Diaz, admitted to government investigators that Schering's claims about crossing the blood brain barrier were false. (Am. Compl., ¶¶ 4, 196.)

- Schering made statements at a conference of oncologists in May 2001 that tests showed Temodar had a favorable survival rate as compared to a placebo, even though the test results did not support this statement, thus misrepresenting to thousands of oncologists and other cancer treatment professionals that Temodar was efficacious. (Am. Compl., ¶¶ 185-188.)

- Schering also promoted Temodar as effective in treating brain metastases, despite test results to the contrary from Schering-conducted Study 086 and internal acknowledgments that "nothing works for melanoma brain mets." (Am. Compl., ¶ 190.)

- Intron A was promoted as effective in treating conditions such as Peyronie's disease and Hepatitis C in patients with normal liver enzymes, despite the lack of evidence supporting such claims, and Schering deliberately confused doctors by setting up internet chat rooms where sales representatives could post that studies concluding that Intron A did not prolong life were flawed because the drug "wasn't given at a high enough dose or for long enough" in the studies. (Am.

Compl., ¶¶ 181-182.)

- Schering bribed numerous doctors to write off-label prescriptions for the Subject Drugs, in various forms, including paying them cash as a quid pro quo as well as kickbacks, gifts, and remunerations disguised as fees for activities such as speaking engagements, clinical trials and consulting. (Am. Compl., ¶¶ 217-295.)

- Schering bribed Prescription Benefit Managers [PBMs] to put the Subject Drugs on TPP formularies, thus increasing Subject Drug prescriptions for TPP beneficiaries (Am. Compl., ¶¶ 299-304.)

This abundance of detail regarding Schering's marketing practices coupled with the averred prevalence of off-label prescriptions for the Subject Drugs coalesces in several key allegations in the Amended Complaint:

> 125. Schering's false marketing scheme was aimed at all levels of the pharmaceutical prescription chain. This included, among others, the FDA, TPPs, PBMs, all medical professionals and quasi-professionals, and individual patients. Schering knows TPPs pay for the Subject Drugs. Schering intended that Named Plaintiffs receive and rely upon the false and misleading statements that Schering put forth to market and sell the Subject Drugs. It was more than reasonably foreseeable that Named Plaintiffs would receive and rely upon Schering's false and misleading statements.
>
> 126. All channels of reliable medical information had been thoroughly corrupted by Schering's multimillion-dollar-a-year, illegal marketing scheme. This was the intended result of Defendants' scheme.
>
> 127. During the Class Period, the Named Plaintiffs purchased the Subject Drugs for ineffective or unsafe off-label uses on

> account of Schering's promulgation of false and misleading information in its massive off-label marketing campaign, causing Named Plaintiffs to suffer damages.
>
> 128. Named Plaintiff BCBSAL paid over $41 million for the Subject Drugs during the Class Period, representing hundreds of thousands of prescriptions written for its members. Named Plaintiff UAI paid millions more for the Subject Drugs during the Class Period, representing thousands of prescriptions written for its members. Named Plaintiff Local 472/172 Fund had at least 15 patients use Intron Franchise Drugs (totaling 190 prescriptions) and at least 3 patients use Temodar therapy (42 prescriptions). Named Plaintiff Local 331 Fund had at least 2 patients who were prescribed the Intron Franchise Drugs.
>
> 129. It is reasonable to infer, and unreasonable not to infer, that at least some of the hundreds of thousands of patients and hundreds of thousands of prescriptions written for Named Plaintiffs' members relating to the Subject Drugs were written off-label as a result of Schering's false claims that, e.g., Temodar crossed the blood-brain barrier. **Eighty-five to ninety-five percent of Temodar's annual sales during the Class Period was off-label** . . . Over thirty percent (30%) of Intron's annual sales during the Class Period was also driven by prescriptions in off-label indications.

(Am. Compl., ¶¶ 125-129 (emphasis in original).) Named Plaintiffs, in short, allege that the deliberately widespread nature of Defendants' marketing scheme supports the inference that some portion of prescriptions for the Subject Drugs paid for by the TPPs were written for off-label indications as a result of Schering's unlawful marketing. They argue in their brief that "Defendants' 'false statements plus bribery' plan caused Plaintiffs to pay for ineffective drugs." (Pl. Br. at 8.)

Despite the unquestionable detail in the Amended Complaint concerning the tactics employed by Schering in marketing the Subject Drugs, the allegations still fail to establish that Named Plaintiffs suffered injury fairly traceable to the misconduct at issue. In other words, the Amended Complaint does not contain factual allegations that support Named Plaintiffs' conclusion that they paid for off-label prescriptions written for the Subject Drugs as a result of the unlawful marketing practices described in the pleading. Some plausible showing of having been personally harmed by Defendants' conduct is fundamental to each Named Plaintiff's standing to pursue this action under Article III, but it remains a noticeable absence in the Amended Complaint. The deficiencies in Named Plaintiffs' demonstration of are two-fold. First, not one of the four TPPs bringing this action alleges that it overpaid for a Subject Drug in some actionable manner, meaning that the drug was worth less than what was paid due to the alleged falsity of the off-label promotional claims made by Schering. Second, despite averring that they paid for off-label prescriptions, Named Plaintiffs fail to link their off-label purchases to the wrongdoing charged in the Amended Complaint, specifically to misrepresentations about the Subject Drugs and/or to conduct characterized as bribery.

The first deficiency, of course, goes to the issue of harm or loss. Accepting, for purposes of this motion, part of the inference Named Plaintiffs allege in the Amended Complaint - that is, that off-label prescriptions for the Subject Drugs were written for Named Plaintiffs' members - the Court discerns no factual allegations stating that the drugs were purchased for indications for which they were actually ineffective or unsafe, as opposed to indications for which they simply had not been FDA-approved. To state cognizable injury, it is not enough that Named Plaintiffs paid for off-label prescriptions. As this Court held in reviewing the original Complaint, to state

that they suffered injury-in-fact, Plaintiffs must "allege facts to support the theory that the named TPPs actually paid for one or more of the Subject Drugs to treat an off-label indication for which the drug was ineffective." Schering I, 2009 WL 2043604, at *15. The alleged inferiority of the Subject Drugs to treat various off-label indications hinges, with one exception, on a Named Plaintiffs' position that there was a lack of scientific and/or clinical data to support Schering's promotional claims regarding the Subject Drugs' ability to perform a certain way or to treat a particular condition. Insufficient data to prove effectiveness is, as the Court has already observed, not the same as actual ineffectiveness.[4]

The Court has emphasized, in this Opinion and in the July 10, 2009 Opinion, that an averment that Schering promoted the Subject Drugs for off-label uses is not tantamount to an averment that it marketed them based on false or misleading information. The deficiency in pleading fraud, and thus in pleading any injury by virtue of having paid for off-label prescriptions, persists here. Named Plaintiffs claim that there was no factual basis to support Defendants' off-label promotional claims about the Subject Drugs and their payment for the Subject Drugs prescribed for these unproven indications represents concrete injury. However, a careful review of the Amended Complaint reveals that these assertions are rooted in Named Plaintiffs' view that studies Schering conducted on the Subject Drugs' ability to treat certain conditions were inadequate to support the promotional claims in a reasonably scientific manner. Named Plaintiffs' position on what might constitute a study that was sufficiently large and/or

[4] Suppose, hypothetically, that subsequent double-blind testing demonstrated that the product was indeed safe and effective for the off-label use promoted by Schering. In Named Plaintiffs' view, they would still have a RICO cause of action despite the fact that the product actually performed as represented.

sufficiently peer-reviewed to provide a solid factual foundation for an off-label indication is a far cry from pleading that the Subject Drugs were in some way not appropriate to treat a condition and fraudulently marketed by Schering to the contrary.[5]

Of the four Subject Drugs in question, only one - Temodar - is connected to any factual assertion that a promotional claim made by Schering to sell the drug was false. The Amended Complaint alleges that Schering knew it could not cross the blood brain barrier yet made the representation that it could in marketing the drug . The alleged "misrepresentations" as to the other drugs' effectiveness, however, have to do with promotional claims Named Plaintiffs maintain were not adequately supported by scientific data rather than with any factual assertion that the claims made were actually false or incorrect. This misses the mark of what constitutes an invasion of *Named Plaintiffs'* legal rights - that is injury to them - as opposed to a wrong recognized under federal law as a general public harm, with the right of enforcement reserved to the government agency regulating pharmaceutical companies.[6]

---

[5] Indeed, as pointed out by Defendants in their brief, off-label treatments cast by Named Plaintiffs as fraudulently promoted were included in the medical compendia and/or were supported by the medical literature at the time. (See Def. Br. at 3-4, 14-15.) (The compendia are reference publications listing medically-accepted pharmaceutical indications and treated as authorities by the Department of Health and Human Services on matters of reimbursement and coverage.) Though this fact does not appear in the Amended Complaint, and does not factor into the Court's holding on this motion to dismiss, the Court believes that judicial notice is warranted, if only to underscore the difference between off-label claims about a drug and those which are false or plainly contradicted by science.

[6] The Court must make the observation that much of Named Plaintiffs' argument in defense of their Amended Complaint continues to rely on the mere off-label promotion of the Subject Drugs. Such "illegal marketing" harmed the TPPs, they contend, because it drove up sales in a way that promotion for FDA-approved uses simply could not achieve. (See, e.g., Am. Compl., ¶¶ 302-314.) This argument misses the point of what kind of harm is redressable by this Court under any of the legal theories of recovery pled by the Amended Complaint. Off-label promotion may run afoul of the FDCA, but it does not by itself necessarily constitute fraudulent

The second deficiency goes to causation, an essential prong of Article III standing. The Amended Complaint fails to set forth facts that trace an off-label purchase, assuming one were to constitute injury-in-fact, to the challenged conduct of which Schering is accused. Named Plaintiffs aver that they made off-label purchases, because they in fact paid for Subject Drug prescriptions and because such substantial portion of the prescriptions written during the Class Period were for off-label indications (approximately 90% of Temodar prescriptions and 30% of Intron Franchise drug prescriptions). (See Am. Compl., ¶¶ 19-22.) They also aver that Schering was engaged in the unlawful promotion of the Subject Drugs during this time period. Named Plaintiffs have pled various and detailed facts about Schering's behavior in the marketplace with respect to its off-label promotion of the Subject Drugs. They have also pled that TPPs generally, among others, were the intended targets of Schering's "misrepresentation plus bribery" scheme employed to induce doctors to prescribe the Subject Drugs. What their allegations do not accomplish, however, is to meet the threshold requirement of connecting the Named Plaintiff TPPs' purchases of the Subject Drugs with the alleged fraudulent promotion and/or bribes.

Named Plaintiffs' attempt to make that essential connection falls short of the plausibility standard applicable at the pleadings stage of litigation. Lacking facts to link prescriptions they paid for with misrepresentations about the safety or efficacy of a Subject Drug, Named Plaintiffs urge the Court to make an inference, but the inference is unsupported by the Amended

---

conduct. See Schering I, 2009 WL 2043604 at *9-10; see also In re Actimmune Mktg. Litig., 614 F.Supp.2d 1037, 1051 n.6 (N.D. Cal. 2009 ("off-label marketing of an approved drug is itself not inherently fraudulent"); In re Epogen & Aranesp Off-Label Mktg. & Sales Practice Litig., 590 F.Supp.2d 1282, 1290 (C.D. Cal. 2008) ("[T]he FDA provides no private right of action for violations thereof, and what the FDCA does not create directly, RICO cannot create indirectly.")

Complaint's factual assertions. They argue that the mere volume of purchases of Subject Drugs they made requires the Court to conclude that those purchases must be causally connected to the fraudulent marketing averred in the Amended Complaint. The allegations, however, provide insufficient information to support the conclusion that some portion of the prescriptions paid for by Named Plaintiffs have anything to do with any alleged misrepresentations about off-label indications for the Subject Drugs.

The Amended Complaint asserts that between 85% and 95% of the prescriptions for Temodar and 30% of the prescriptions for Intron Franchise Drugs were for off-label uses. It is not a foregone conclusion from these figures that all of these off-label prescriptions were written for indications that are at issue in Named Plaintiffs' allegations that Schering's marketing conduct was deceitful. The pleading lacks any information regarding whether the Subject Drugs have off-label uses other than those underlying the misrepresentation allegations. If they do, then concluding that Named Plaintiffs must have paid for off-label prescriptions that are fairly traceable to the promotional claims challenged here would require information - also lacking - about whether those other indications are in the compendia and the extent to which prescriptions were written for medically-accepted off-label uses.

Failure to connect purchases to allegedly false marketing claims is only one piece of the Amended Complaint's deficiency with respect to establishing Named Plaintiffs' standing. The wrongdoing alleged also includes various activities classified as "bribery" by Named Plaintiffs in the Amended Complaint and in their brief in opposition to this motion. According to the Amended Complaint, the unlawful inducements given to doctors to prescribe the Subject Drugs for off-label uses consisted of the following: Schering paid physicians purportedly for speaking

engagements, but in reality the payments were rewards for prescribing the Subject Drugs. It covered hotel and travel expenses for physicians and guests in connection with these engagements. It made payments to physicians for teaching Schering sales representatives about technical aspects of their medical practices. Schering entered into consulting agreements with various physicians without a clear expectation of what kind of services would be performed for compensation. Physicians were paid to conduct clinical trials, but the purpose of these trials, which are described in some detail in the Amended Complaint, was not research but rather boosting sales of the Subject Drugs by encouraging physicians to enroll patients in the trials and to write more prescriptions. Schering provided free or discounted Subject Drug samples to physicians, who then charged patients and/or TPPs full price for the samples. Sales representatives gave physicians grants, which were ostensibly for research or education, informing physicians they could use the money however they wished. Schering provided medical practices with physicians assistants or nurses free of charge. The nurses, or "Patient Care Consultants", ostensibly placed to provide patient support in treatment regimens really served to maximize sales of Subject Drugs. The Amended Complaint charges one particular physician in Florida with receiving a "straightforward kickback" for prescribing Temodar in the form of a fishing excursion hosted by a Schering sales representative. (See, generally, Am. Compl., ¶¶ 217-295.)

Labeling such remunerations and gifts as bribes appears in large part to amount to a legal conclusion, especially given the absence of details regarding specific instances of payment. Nevertheless, for purposes of examining whether the Amended Complaint establishes some minimal causal link between Named Plaintiffs' purported injury and the misconduct, the Court

will assume that Named Plaintiffs' characterization of these activities as bribery is fitting. See Warth, 422 U.S. at 500 ("standing in no way depends on the merits of the plaintiff's contention that particular conduct is illegal . . . ."). Although the Amended Complaint identifies certain physicians who accepted "bribes" in return for writing off-label prescriptions, it does not allege that any doctor who wrote Subject Drug prescriptions for a Named Plaintiff's beneficiary did so in return for cash or gifts from Schering. Apart from failing to connect any prescriptions paid for by Named Plaintiffs to particular doctors alleged to have taken bribes, the Amended Complaint gives no indication as to the volume of doctors in general who were allegedly writing off-label prescriptions for the Subject Drugs based on Schering's inducements. There is not even the slightest suggestion of how widespread the bribery was. All that is known from the Amended Complaint is that a handful of doctors, out of presumably hundreds nationwide prescribing the Subject Drugs, received bribes disguised as legitimate remunerations. It is impossible to infer from these seemingly isolated incidents that similar approaches were pursued by Schering with other doctors and, moreover, with so many other doctors that it would be reasonable to infer that some prescriptions paid for by the Named Plaintiffs are fairly traceable to the alleged wrongdoing.

The Court does not intend to convey any approval of Schering's marketing methods as described in the Amended Complaint. Assuming the truth of the factual allegations presented to the Court in the instant action, Schering's conduct in promoting the Subject Drugs was, to put it mildly, egregious. The allegations, to the extent that they are correct, portray a company which pursued monetary profits, with callous disregard for its obligations to society and to the medical community.

Nevertheless, this Court's role is to apply the appropriate legal principles impartially in reviewing the pleading filed with this Court and in assessing the rights of the parties before it to proceed with litigation. It must leave the task of pursuing appropriate punishment, when justified, to the bodies entrusted by our government with such responsibility. Indeed, as Named Plaintiffs repeatedly point out in their papers, Schering has been subjected to criminal and civil penalties as a result of conduct which is subsumed in the Amended Complaint.

The question before this Court is not whether Schering deserves to be sanctioned. It is whether Named Plaintiffs have demonstrated, based on the allegations of the Amended Complaint, that they are parties entitled to seek civil relief in a court of law according to the minimal jurisdictional requirements of Article III. The problem with the viability of the Amended Complaint remains one of disconnect between the Named Plaintiffs' payment for off-label prescriptions and the alleged misconduct by Defendants. The link is not explicitly made, nor do Named Plaintiffs plead factual allegations that might elevate the connection above mere speculation.

The Court wishes to make clear that it has not, in examining the sufficiency of the Amended Complaint to establish Named Plaintiffs' standing, held the pleading to the task of proving the substantive claims for relief. At this stage of the litigation, evidence of injury, causation and wrongdoing is not demanded. What is required, however, are factual allegations which, taken as true, show that the four TPPs who have filed this Amended Complaint and have asked the Court for relief have at a minimum sustained an injury cognizable under Plaintiffs' legal theories and traceable to the complained-of wrongdoing by Defendants. The facts alleged in the Amended Complaint, however, call for the Court to speculate that Named Plaintiffs must

have been injured as a result of Schering's unlawful marketing tactics.[7] For the reasons expressed above, this Court concludes that at best, the Amended Complaint suggests the possibility that the Named Plaintiffs were harmed by the subject marketing scheme. This possibility of harm is simply not enough to establish standing. Accordingly, the Court will dismiss the RICO claims asserted in Counts I and II of the Amended Complaint pursuant to Rule 12(b)(1) for lack of jurisdiction.

### C. Common Law Claims

Defendants also argue lack of standing as grounds for the dismissal of the Amended Complaint's two common law tort claims of interference with contractual relations and unjust enrichment. For the same reasons as discussed above, the Court finds that Named Plaintiffs have failed to demonstrate that they have suffered injury-in-fact fairly traceable to Defendants' alleged misconduct and likewise concludes that these common law claims must be dismissed under Rule 12(b)(1). The Court also feels compelled to address Defendants' argument in the alternative, that even if standing were established as to these claims, they would fail under Rule 12(b)(6). Assuming, *arguendo*, the existence of Article III standing to pursue the common law claims pled in the Amended Complaint, it would merely satisfy the "irreducible constitutional minimum" of this Court's jurisdiction. It would not, however, entitle Named Plaintiffs to pursue those claims

[7] This deficiency in pleading harm personally sustained by each Named Plaintiff is not, moreover, cured by allegations that the entire pharmaceutical market was targeted by the scheme and that the unlawful tactics described had corrupted all channels of information. These allegations amount to no more than a "fraud of the market" theory of loss, expressly rejected by the Court in the July 10, 2009 Opinion.

if, as Defendants have argued, the Amended Complaint fails to state that Named Plaintiffs could plausibly obtain such relief.

The elements of a claim for tortious interference with a contractual relationship under New Jersey law[8] are as follows: (1) plaintiff had an existing contract or reasonable expectation of economic benefit or advantage; (2) the defendant knew of the contract or expectancy; (3) the defendant wrongfully interfered with that contract or expectancy; (4) it is reasonably probable that the loss of the contract or prospective economic gain was a result of the interference; and (5) damages resulted from the interference. Florian Greenhouse, Inc. v. Cardinal IG Corp., 11 F.Supp.2d 521, 525-26 (D.N.J. 1998); see also Printing Mart-Morristown v. Sharp Elec. Corp., 116 N.J. 739, 751-52 (1989) (identifying elements). The interference contemplated by the cause of action goes to a failure to perform under the contract. DiGiorgio Corp. v. Mendez and Co., Inc., 230 F.Supp.2d 552, 566 (D.N.J. 2002). "[O]ne interferes with a contract only where he causes a party not to perform under it." Id.

Named Plaintiffs base the tortious interference claim on the theory that Schering's marketing scheme disrupted contracts between patients and the TPPs as well as the "contract-like expectations between patients and their prescribing doctors." (Pl. Br. at 38.) Specifically, the Amended Complaint alleges that Named Plaintiffs placed the Subject Drugs on their formularies - lists of drugs that have been approved for coverage - as a result of Defendants' improper marketing. (Am. Compl., ¶¶ 117-123.) They also allege loss because physicians prescribed the

[8] The Court's authority to hear the common law claims is grounded in diversity jurisdiction under the Class Action Fairness Act, 28 U.S.C. § 1332(d). (See Am. Compl., ¶ 55.) It is well-settled that a federal court exercising diversity jurisdiction must apply state substantive law. See Erie R. Co. v. Tompkins, 304 U.S. 64 (1938).

Subject Drugs for their patients as a result of Schering's interference with the "contract" between patient and doctor. (Id., ¶¶ 124-125.) These disruptions, the Amended Complaint avers, caused the TPPs to pay for the Subject Drugs for off-label use.

As Defendants have argued, Named Plaintiffs fail to allege that their contracts with patients to pay for drugs listed on formularies were breached as a result of Defendants' malicious interference. No actionable interference is stated. To the extent the tortious interference is premised on the effect of the marketing scheme on physicians' prescribing decisions, it is even more attenuated. Putting aside the questions of whether the physician-patient relationship can be deemed contractual within the meaning of this cause of action, and whether the Named Plaintiffs had a reasonable expectation of benefit related to that "contract," Named Plaintiffs' pleading is again plagued by a failure to allege that physicians writing prescriptions for Subject Drugs paid for by Named Plaintiffs altered their behavior and breached the contract as a result of the alleged wrongdoing. Named Plaintiffs, in short, fail to allege breach of any existing contract to which they were either a party or had an expectation of economic benefit. Their theory of wrongdoing by Defendants - that their marketing scheme so corrupted all channels of information and distribution that these TPPs covered the Subject Drugs when they otherwise would not - does not even remotely allege a failure to perform, much less allege actionable interference with contract according to the plausibility standard of Twombly and Iqbal. This flaw is fatal to the claim for tortious interference with contract.

The failure of Named Plaintiffs' claims for legal relief compels the dismissal of their claim for an equitable remedy for unjust enrichment. A claim for unjust enrichment provides an equitable remedy to a plaintiff who has conferred a benefit on the defendant when the

defendant's retention of that benefit without payment would be unjust. VRG Corp. v. GKN Realty Corp., 135 N.J. 539, 554 (1994). Having failed to allege a violation of *their* rights under any cognizable theory of relief, Named Plaintiffs do not establish how it would work an injustice for Defendants to retain the money paid by Named Plaintiffs for the Subject Drugs. See Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc., 171 F.3d 912, 936-37 (3d Cir. 1999) (holding that, where tort claims cannot be maintained, rationale for permitting equitable action for restitution also disappears, given lack of underlying wrong on which to premise equitable claim).

Accordingly, the common law tort claims asserted at Counts III and IV of the Amended Complaint will be dismissed pursuant to Rule 12(b)(1) and, alternatively, pursuant to Rule 12(b)(6) for failure to state a claim upon which relief may be granted.

## III. CONCLUSION

For the foregoing reasons, the Court will dismiss the Amended Complaint in its entirety pursuant to Rules 12(b)(1) and 12(b)(6). An appropriate form of Order will be filed with this Opinion.

s/Stanley R. Chesler
STANLEY R. CHESLER
United States District Judge

DATED: June 9, 2010